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New claims 35-38 have been added and are fully supported. The new claims do not introduce new matter.

**ANTICIPATION**

Examiner asserts that claims 24-26 and 28-29 are anticipated by US 5,296,472 to Sanchez, et al. Examiner's entire basis for the alleged anticipation is that Sanchez's method inherently reduces the production of sebum in skin or hair.

Examiner asserts the following:

- Sanchez discloses methods for delipidation of skin and/or hair.
- Sanchez discloses the effective amounts of cyclodextrin component.

From this examiner concludes that Sanchez's method inherently reduces the production of sebum. Further, it is concluded without reasons or evidence that reducing sebum production is an inherent property in the administration to skin of the cyclodextrin compositions.

**Examiner's Rationale**

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Examiner has not provided any rationale or evidence for maintaining a rejection under an inherency theory. See MPEP § 2112.

For legal support, Examiner cites cases that do not fall within the facts presented her . In *Nowitski* and *Barr Labs*, the claimed methods at issue were held to be inherent by methods taught in the references. However, this is not the case her .

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In *Novitski*, the Board held that a prior art reference could anticipate under an inherency theory because the reference disclosed a method that was expressly demonstrated to prevent the growth of certain nematodes in plants. Thus, the Board found it would inherently prevent the growth of other nematodes.

In *Barr Labs*, the Fed Circuit held that claims to a method of inhibiting serotonin uptake with the drug fluoxetine, were invalid because the method was inherent to earlier claims for treating anxiety with the same drug. The Fed Circuit reasoned that persons in the art knew that fluoxetine administration for anxiety would have inherently inhibited serotonin uptake during the process of treating anxiety.

~~The facts in Barr and Novitski are very similar to Sanchez's Rejection~~

The difference in *Barr* and *Novitski*, is that it was known with certainty that the formulations in question would, (a) be available at the necessary site of action, and that (b) the formulation would likely have the particular metabolic effect. In other words, the nematocidal formulation was known to reach infecting nematodes and kill them. In *Barr*, fluoxetine was known to reach the nervous system, specifically the brain, where serotonin functions.

In contrast, neither Sanchez nor the Examiner provides evidence that cyclodextrins are (a) known to reach the sebaceous glands and (b) have the desired metabolic effects. In

For this reason, Examiner's conclusory statements do not constitute a *prima facie* case of inherency. The facts underlying the instant rejection are not similar to these cases. Sanchez does not state or demonstrate that cyclodextrins effect sebum production nor is it likely that his methodology results in affecting sebum production. To understand why this is so, Examiner's attention is drawn to Exhibit I.

Exhibit I is a schematic of the relationships of the epidermis and dermis to each other. The location of the sebaceous glands, the site of sebum production is indicated as being in the dermis, below the epidermis. On the other hand, the sebum accumulates on

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the epidermal surface. Thus, to have an effect on sebum production, the method of Sanchez must permit the cyclodextrin to reach the sebaceous gland for a length of time sufficient to effect sebum production. It is suggested that Sanchez provides no indication that any sub-epidermal tissues or cells are effected by his method.

Without such a showing, It cannot be concluded that Sanchez's cyclodextrin treatment necessarily effects sebum production.

In fact, his claimed method clearly demonstrates that cyclodextrins only directly delipidate the surface buildup of lipids. This is evident because the composition is left in place only until the lipoidal build-up is penetrated. See, claim 1, clause (2). Therefore, Sanchez teaches and claims that the composition may be removed after it penetrates, solubilizes or loosens the unwanted lipoidal matter.

This is illustrated in Sanchez's other examples, where he either examines the only solubility of lipids with cyclodextrins, or treats the skin of subjects with the cyclodextrins and makes observations as quickly as a few minutes. This is because it is only by direct delipidation of the skin that Sanchez claims to control the excessive buildup of sebum and other oily lipids. Col. 3, lines 60-63.

Sanchez states that his formulations can delipidate the hairshaft and surrounding skin. Col 5, lines 52+. Without acknowledging that cyclodextrins reach the root of the hair where the sebaceous glands are located, his method cannot inherently effect sebum production.

In sum, Examiner's Inherency theory is invalid because it cannot reasonably be demonstrated or reasoned that Sanchez's method necessarily effects sebum production.

Therefore, the rejections under § 102 should be withdrawn.

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**OBVIOUSNESS**

**Claim 27**

Claim 27 is alleged to be obvious over Sanchez. The rationale provided is that it would have been obvious to persons in the art to optimally adjust by routine experimentation, the wt.-% of  $\gamma$ -cyclodextrin relative to the other cyclodextrins. See office action, bottom of page 4.

Examiner is respectfully reminded that a parameter, such as the wt.-% of  $\gamma$ -cyclodextrin relative to the other cyclodextrins, must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977); see MPEP § 2144.05.

It is noted that the undersigned believes that Examiner may have misread claim 27. The 30 wt.-% of  $\gamma$ -cyclodextrin was in relation to the total cyclodextrin component, and not the composition's total weight. Sanchez does not suggest this claim element as being a result-effective variable.

However, if Examiner has not misread the claim, it is requested that the following remarks be considered.

It is respectfully suggested that Examiner has not provided any evidence or reasoning that Sanchez discloses or believes that, specifically, the concentration of  $\gamma$ -cyclodextrin relative to the  $\alpha$ , and  $\beta$  cyclodextrins is result-effective. In fact, the opposite is true, e.g., see col. 7, lines 39-52. Sanchez indicates that any one can be used alone (lines 39-41), or in various combinations.

Respectfully, Examiner's rationale bridging pages 4 and 5 is not sufficient to maintain the rejection, because it simply restates that any of the cyclodextrins may be present in any concentration. However, there is no indication that at least 30% of the cyclodextrins should be  $\gamma$ -cyclodextrin.

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Accordingly, claim 27 is not obvious and the rejection may be properly withdrawn.

**Claims 30-34**

As a general remark, Applicants point out that there has not been a single reference applied in this case that discloses cyclodextrins in an oil-containing composition for treating and preventing sebum buildup. Thus, on this basis alone, claims 30-34 cannot be *prima facie* obvious. The reason is that because Sanchez merely alludes to the possibility of adding small amounts of lipophilic materials. However, the preferred embodiments are oil-free. There is no suggestion to modify Sanchez to arrive at the claimed subject matter.

For arguments sake only, if we assume that Sanchez fairly suggests that a certain amount of oil phase is permissible, what is the composition of this oil phase? Given the unusual chemistry of cyclodextrins, and Sanchez's preference for maintaining the cyclodextrins in an "uncomplexed" state (i.e., not bound to lipids; top of col 2) where does Examiner find the motivation to combine certain lipophilic compounds with the cyclodextrins. Respectfully there is no motivation to make these combinations because they are not disclosed by Sanchez.

Applicants reiterate the remarks above with respect to the wt.-% of  $\gamma$ -cyclodextrins as Examiner apparently asserts the same argument for claim 32.

Sanchez's disclosure cannot fairly be viewed as teaching or suggesting formulations having an oil phase.

→ All throughout the Sanchez reference he discloses and emphasizes the oil-free and aqueous nature of the composition; see Abstract; col. 2, lines 23 to 45;

→ Examiner has not given sufficient weight to the conflicting teachings of Sanchez: e.g., col. 5, lines 12-21, wherein small amounts of certain lipophilic components is contemplated. However, immediately after this is an expressly stated preference for no oily components at all.

→ Not one of Sanchez's examples employs an oil-phase containing formulation.

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In view of this disclosure, persons with ordinary skill would not have arrived at claims 30-38. In addition, claim 32 and 35-38 especially, are not suggested.

Applicants respectfully suggest that Sanchez by itself does not suggest combining an oil phase with cyclodextrins. Accordingly, the rejection should be withdrawn.

CONCLUSIONS

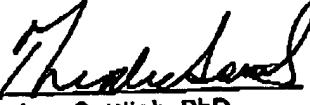
Applicants respectfully point out that Examiner's rejections have been addressed so as to overcome the rejections.

Examiner's inherency argument cannot be sufficient in view of the cases cited and the rules set out in the MPEP.

In addition, Sanchez cannot be fairly read to teach an oil/cyclodextrin combination.

Respectfully Submitted,

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**EXHIBIT 1****A T I O N**

27-year-old male is involved in a gasoline explosion, sustaining burns to the face, neck, chest, and arms. Upon arrival at the emergency room, he complains of intense pain in the face and neck, which exhibit extensive blistering and erythema (redness). These findings are all curiously absent on the burned chest and arms, which have a pale, waxy appearance.

Examination reveals the skin on the patient's chest and arms to be leathery in texture and without sensation, including pain. The emergency room (E.R.) physician comments to an observing medical student that third degree burns are present on the skin of these regions and that excision of the burn eschar (traumatized tissue) with subsequent skin grafting will be required.

Why is the area of second degree burn red, blistered, and painful, while the third degree burn is pale and insensate (without sensations, including pain)? Why will the chest and arms require skin grafting while the face and neck probably will not?

**Hints:** Think in terms of functions of the skin, and survival of the germinal cells in functioning skin. Examine carefully Figures 7.1 and 7.13.

**The Integument as an Organ**

The integument (skin) is the largest organ of the body, together with its epidermal structures (hair, glands, and nail). It constitutes the integumentary system. It has adaptive modifications in certain body areas that accommodate protective or metabolic functions. The integument is a dynamic interface between the continually changing external environment and the body's internal environment and aids in maintaining homeostasis.

**Objective 1.** Explain why the integument is considered an organ and a component of the integumentary system.

**Objective 2.** Describe some common clinical conditions of the integument that result from nutritional deficiencies or body dysfunctions.

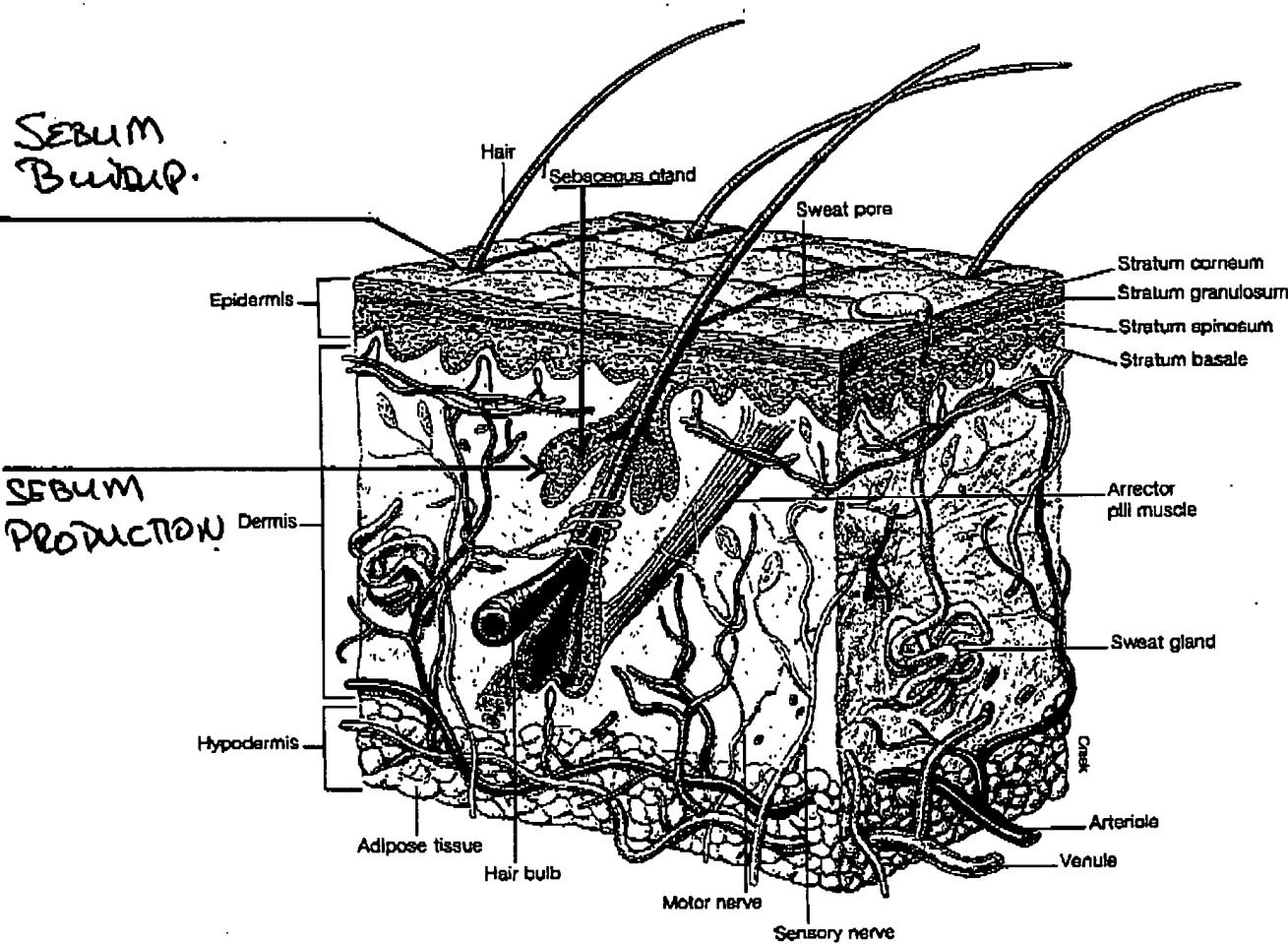


Figure 7.1 A diagram of the skin.